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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,170	09/23/2003	Bruce H. KenKnight	279.565USI	1699
21186 7590 03/02/2007 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER REIDEL, JESSICA L	
			ART UNIT 3766	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/02/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/669,170

Applicant(s)

KENKNIGHT ET AL.

Examiner

Jessica L. Reidel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on December 15, 2006. Claims 3 and 13 have been previously cancelled. Claims 1-2, 4-12 and 14-20 are pending.

Claim Objections

2. In view of the response filed on December 15, 2006, the Examiner has withdrawn the objections to the Claims.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2, 7, 10-12, 17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Darvish. As to Claims 1-2, 10-12 and 20, Darvish discloses an implantable device 70 for delivering cardiac function therapy to a patient for improving a patient's cardiac output and providing cardiac resynchronization therapy through multi-site ventricular pacing (see Darvish Fig. 6, column 1, lines 13-16 and column 7, lines 62-64). The implantable device 70 of Darvish comprising sensing channels and pacing channels for sensing cardiac electrical activity at a plurality of myocardial sites and delivering pacing pulses to a plurality of myocardial sites (i.e. right atrium 28, right ventricle 30 and left ventricle 44) (see Darvish Figs. 1 and 6, column 4, lines 42-53 and column 5, lines 1-16). Device 70 also comprises a control logic unit, read as a

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controller 72 to control the application of electrical energy from electrodes 32, 34 and 46 (see Darvish column 7, lines 65-67) via an algorithm stored in memory 78 (see Darvish column 8, lines 60-64) which defines the pulse output sequence and pulse configuration for delivering cardiac function therapy (see Darvish column 5, lines 1-39). In reference to Darvish Fig. 3, the algorithm programmed into the controller 72 is depicted in flow chart form where the device 70 operates first in a cardiac function therapy (DDI pacing) mode (see Darvish column 6, lines 21-23), periodically assesses the patient's cardiac output, read as assessing the patient's cardiac function, and ceases the current pacing mode or continues the current pacing mode – i.e. the delivery of cardiac function therapy based upon the cardiac function assessment (see Darvish Fig. 3). It is inherent that pacing is suspended during the assessment of the patient's cardiac function since Darvish also discloses that the flow chart depicted in Fig. 3 is a “graduated application” to limit the electrical power that must be applied to the heart to prolong battery life and that the algorithm allows the heart muscle “to function in a natural manner as physiological needs will allow and to rest when enhanced cardiac output is not required” (see Darvish column 6, lines 7-20).

Darvish discloses that the cardiac function therapy may be bi-ventricular pacing, read as multi-site ventricular pacing or “any pacing mode known in the art” (see Darvish column 2, lines 48-54 and column 6, lines 24-29). Darvish further discloses that the multi-site ventricular pacing may comprise multi-site ventricular pacing where the right ventricle 30 is paced 3.5 ms before the left ventricle 44, read as a multi-site ventricular pacing which pre-excites the myocardial regions in the right ventricle 30 (see Darvish column 6, lines 62-67 and column 7, lines 1-8). The Examiner notes that a recitation of the intended use of the claimed invention must result in a

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structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the implantable device 70 of Darvish is capable of pre-exciting the right ventricle 30 in order to redistribute myocardial wall stress during systole for the purpose of reversing ventricular remodeling.

5. As to Claims 7 and 17, Darvish discloses that the cardiac function assessment may include measuring the patient's heart rate variability, which is inherently deterministic of a patient's autonomic balance since heart rate and variations of heart rate are products of both chains of a person's autonomic nervous system (see Darvish column 6, lines 35-41).

6. Claims 4, 6, 14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Darvish. As to Claims 4 and 14, Darvish discloses that cardiac output is assessed to be "adequate" via a signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

7. As to Claims 6 and 16, Darvish discloses that the controller 72 may regulate the pacing algorithm depicted in Fig. 3 responsive to a subject's physical activity by utilizing an accelerometer, read as an exertion level sensor 104 (see Darvish column 9, lines 23-32). It is inherent or at least obvious to one having ordinary skill in the art to compare the output of such exertion level sensor to an exertion level threshold to determine if the pacing algorithm should be modulated or not. Darvish also discloses that cardiac output is assessed to be "adequate" via a

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signal acquired by a physiological sensor sent to controller 72 (see Darvish column 4, lines 1-14). It is also inherent or at least obvious to one having ordinary skill in the art that a determination of a signal being "adequate" is accomplished via a microprocessor 74 within controller 72, which compares the sensed signal to a specified threshold value.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Burnes (U.S. 2004/0220636). Darvish discloses the claimed invention as discussed above except that the physiological sensor for assessing the patient's cardiac output is not specified to be a trans-thoracic impedance measuring circuit.

Burnes, however, teaches that it is well known to provide an assessment of cardiac output of a patient by using an impedance monitor 162 that that measures transthoracic impedance (see Burnes Fig. 4, page 3, paragraph 29 and page 7, paragraphs 64-65). Burnes does not explicitly state why impedance monitor 162 is used, but it appears that impedance monitor 162 is used to provide a means to assess a patient's cardiac output external to or implanted within the body of a patient (see Burnes page 2, paragraph 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method as taught by Darvish, with the transthoracic impedance measuring circuit 162 as taught by Burnes, since such a modification would provide the system and method with a transthoracic impedance measuring for providing a means for cardiac output to be assessed both internally and externally.

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10. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Zhu et al. (U.S. 2002/020306). Darvish discloses the claimed invention as discussed above except that the method carried out by device 70 does not comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value.

Zhu, however, discloses that the LF/HF ration is a good indicator of the state of autonomic balance of a patient and discloses circuitry for measuring and collecting time intervals between successive chamber senses, storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, and computing an LF/HF ratio and triggering a diagnostic mode of the device when the LF/HR exceeds a predetermined ratio threshold value (see Zhu page 5, paragraphs 39-41). It would have been obvious to one having ordinary skill in the art to modify the method and system of Darvish in view of Zhu to comprise circuitry for measuring and collecting time intervals between successive chamber senses and storing the collected intervals as a discrete RR interval signal, filtering the RR interval signal into defined high and low frequency bands, and determining the signal power of the RR interval signal in each of the low and high frequency bands, referred to LF and HF, respectively, and, circuitry for computing an LF/HF ratio and

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assessing cardiac function by comparing the LF/HF ratio to a specified ratio threshold value to acquire means to switch the device from a therapy mode to a diagnostic mode when necessary.

11. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darvish in view of Ding (U.S. 2002/0062139). Darvish discloses that the device 70 comprises a telemetry unit 114 coupled to a bi-directional telemetry coil 116 which generally perform similar functions to those performed by pacemaker telemetry apparatuses known in the art. Darvish discloses the claimed invention as discussed above except that the method carried out by device 70 is not specified to comprise temporarily suspending delivery of cardiac function therapy and assessing the patient's cardiac function upon a command from an external programmer.

Ding, however, discloses an implantable device for delivering cardiac function therapy to a patient (see Ding Fig. 1 and page 2, paragraph 14) comprising atrial and ventricular sensing channels for sensing cardiac electrical activity at a plurality of myocardial sites and atrial and ventricular pacing channels for delivering pacing pulses to a plurality of myocardial sites (see Ding Fig. 1 and page 2, paragraph 15) and a controller 28 made up of a microprocessor 10 communicating with memory 12 and dedicated circuitry for delivering pacing pulses in accordance with a programmed pacing mode (i.e. DDD, DVI, VDD, biventricular or multi-site ventricular pacing) with a defined pulse output sequence and pulse output configuration (see Ding page 2, paragraphs 11 and 14 and page 3, paragraph 16). Ding also discloses that the controller 28 is programmed to temporarily suspend delivery of cardiac function therapy, assess the patient's cardiac function (i.e. monitor changes in the condition of the heart's conduction system by measuring changes in ventricular activation patterns as reflected by electrogram signals detected from different locations in the heart) (see Ding page 1, paragraphs 6-7), and

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either re-initiate or continue the delivery of cardiac function therapy based upon the cardiac function assessment (see Ding Figs. 2-3, page 2, paragraphs 7 and 11 and page 3, paragraphs 16-17). Specifically, the pacing therapy of Ding “may be adjusted accordingly” in view of the cardiac function assessment (see Ding page 3, paragraph 16).

Ding discloses that the controller 28 may be programmed to temporarily suspend delivery of cardiac function therapy (i.e. pacing) and assess the patient’s cardiac function (i.e. changes in the condition of the heart’s conduction system) upon a command from an external programmer via telemetry interface 40 in order to enable an attending physician/clinician to assess whether the patient’s conduction system is improving, deteriorating or remaining unchanged so that pacing may be adjusted accordingly (see Ding page 2, paragraphs 13-14 and page 3, paragraph 16 and Claim 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Darvish in view of Ding such that the step of temporarily suspending delivery of cardiac function therapy and assessing the patient’s cardiac function is done on command issued by an external programmer in order to enable an attending physician/clinician to assess to have control over the implanted device’s operating functions after assessing whether the patient’s conduction system is improving, deteriorating or remaining unchanged.

Response to Arguments

12. Applicant's arguments filed December 15, 2006 have been fully considered but they are not persuasive. In response to Applicant’s argument that Darvish does not “teach or suggest” for temporarily suspending cardiac function therapy at periodic intervals, assessing the cardiac

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function while the cardiac function therapy is suspended and either ceasing or continuing the cardiac function therapy based upon the cardiac function assessment (see page 6 of the Remarks), the Examiner respectfully disagrees. Although not explicitly stated by Darvish, such operation *is inherent* as previously discussed [emphasis added]. The algorithm programmed into the controller 72 of Darvish is depicted in flow chart form (see Darvish Fig. 3) where the device 70 operates first in a cardiac function therapy (DDI pacing) mode (see Darvish column 6, lines 21-23), periodically assesses the patient's cardiac output, read as assessing the patient's cardiac function, and ceases the current pacing mode to switch to another pacing mode or continues the current pacing mode – i.e. the delivery of cardiac function therapy based upon the cardiac function assessment (see Darvish Fig. 3).

It is *inherent* that pacing is suspended during the assessment of the patient's cardiac function. Darvish expressly specifies that the flow chart depicted in Fig. 3 is a “graduated application” in an effort to limit the electrical power that must be applied to the heart. Darvish specifies that this “graduated application” prolongs battery life. Furthermore, Darvish specifies that the graduated progression from mode to mode, as discussed above in reference to Darvish Fig. 3, is decided based analysis of criteria such as “heart rate”, “detection of arrhythmia's” and/or “statistical heart rate variability” and goes on to further specify that the algorithm allows the heart muscle “to function in a natural manner as physiological needs will allow and to rest when enhanced cardiac output is not required” (see Darvish column 6, lines 7-20). This, in combination, is interpreted by the Examiner to show that it is inherent that no pacing therapy is being applied when the heart is “to function in a natural manner as physiological needs will

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allow” or when the patient’s natural heart rate is being sensed for the purpose of making decisions as to the graduation of the therapy and to prolong battery life.

According to the MPEP § 2112.01, “When the PTO shows a sound basis for believing that the products of the Applicant and the prior art are the same, the Applicant has the burden of showing that they are not”. *In re Spada*, 911 F.2d 705, 709 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant’s traversal of the rejections made by the Examiner are not supported by any evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product and therefore are not found to be persuasive. The Examiner was unable to find throughout the Applicant’s Arguments/Remarks, evidence as to why the Examiner’s rationale was incorrect and/or false.

In response to Applicant’s Argument that the intent of Darvish is not to reverse cardiac remodeling (see page 7 of the Remarks), it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). As previously discussed, Darvish expressly discloses that the cardiac function therapy may be bi-ventricular pacing, read as multi-site ventricular pacing or “any pacing mode known in the art” (see Darvish column 2, lines 48-54 and column 6, lines 24-29). Darvish further expressly discloses that the multi-site ventricular pacing may comprise multi-site ventricular pacing where the right ventricle 30 is paced 3.5 ms *before the left ventricle* 44, read as a multi-site ventricular pacing which pre-excites the myocardial regions in the right ventricle 30 (see Darvish column 6, lines 62-67 and column 7, lines 1-8) [emphasis added]. Since the pacing therapy is the same as Applicant’s where the right ventricle 30 is pre-

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excited, Darvish is capable of redistributing myocardial wall stress during systole for the purpose of reversing ventricular remodeling.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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